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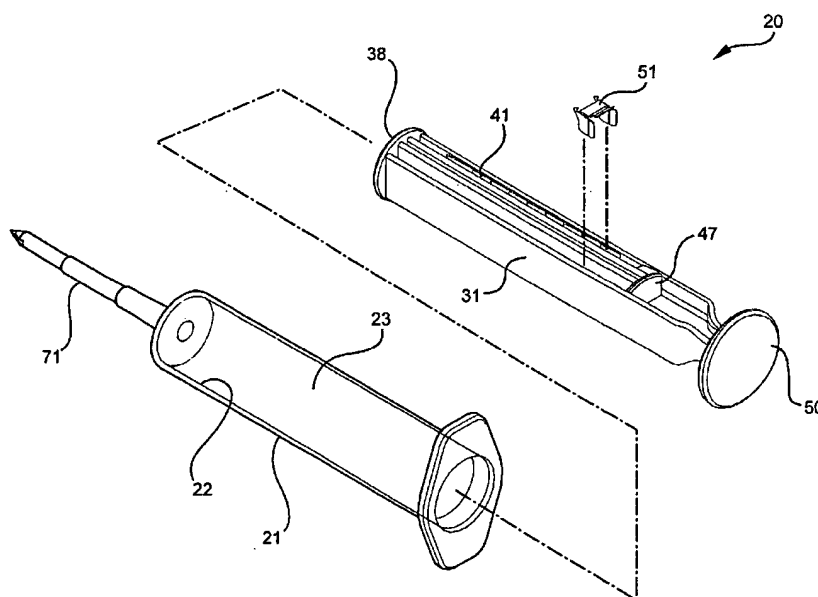
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(54) Title: SINGLE-USE SYRINGE



(57) Abstract: An operable single-use syringe includes a barrel having an inside surface defining a chamber for retaining fluid and an open proximal end. A plunger rod having an elongate body portion and a stopper at its distal end slidably positioned in fluid-tight engagement in the barrel. A locking element is positioned in the barrel between the plunger rod and the inside surface of the barrel. The locking element has a base and two leg members projecting therefrom that are positioned in longitudinal grooves in the plunger rod. The locking element only moves distally in the barrel and prevents re-use of the syringe after its contents have been discharged.

5

## SINGLE-USE SYRINGE

## BACKGROUND OF THE INVENTION

The present invention relates to syringe assemblies and particularly to syringe assemblies having an automatic disabling mechanism.

10 Throughout the world the multiple use of hypodermic syringe products which are intended for single-use only, is instrumental in drug abuse and in the transfer of contagious diseases. Intravenous drug users who routinely share and re-use syringes are a high-risk group with respect to the AIDS virus. Also, the effects of multiple use are a major concern in some countries where repeated use of syringe products during mass immunization programs  
15 may be responsible for the spread of many diseases. Re-use of single-use hypodermic syringe assemblies is also instrumental in the spread of drug abuse even in the absence of infection or disease.

Many attempts have been made to remedy this problem. Most notable are early contributions which relies on a specific act to destroy the syringe after use either by using a  
20 destructive device or providing syringe assembly with frangible zones so that the syringe could be rendered inoperable by the application of force. Other attempts involve the inclusion of structure which would allow the destruction or defeating of the syringe function by a conscious act of the syringe user. Although many of these devices work quite well, they require the specific intent of the user followed by the actual act to destroy or render the  
25 syringe inoperable. These devices are not effective with a user having the specific intent to re-use the hypodermic syringe. Accordingly, there was a need for a single-use hypodermic syringe which after use will become inoperable or incapable of further use automatically without any additional act on the part of the user. The automatic function is much harder to provide because the means for rendering the syringe inoperable must not prevent its filling or  
30 use under normal conditions.

Single-use syringes which automatically disable after injection are taught in the art. Some of these syringes contain a locking element positioned in the syringe barrel between the plunger rod and the inside surface of the barrel. In use, the syringe allows the user to draw a pre-selected amount of medication into the chamber of the barrel and deliver this medication,  
35 as through injection, into the patient. Any attempt to withdraw the plunger to use the syringe a second time will cause the locking element to embed itself into the inside surface of the barrel to prevent proximal motion of the plunger rod.

5 Many times a traditional multi-use syringe and needle assembly are used to reconstitute lyophilized medication. The steps for reconstitution include withdrawing sterile water from a stoppered vial or glass ampoule into the syringe barrel and then delivering this water into a stoppered vial or glass ampoule containing the lyophilized medication. The reconstituted medication is then drawn into a single-use syringe for delivery to the patient.

10 Single-use syringes designed specifically for reconstitution and which cannot be used for injecting medication into a patient are not presently available.

Further, mass immunization programs usually take place in developing countries where resources are limited. Accordingly, sometimes with limited resources a number of people immunized can be increased if the cost of the medication and/or the syringe is

15 reduced. It is not desirable to reduce the cost of the single-use syringe by compromising its features since those intent on re-using syringes can be very aggressive and resourceful in their attempts to disable the safety features.

Accordingly, there is always a need for single-use syringes which are more cost-effective and more resistant to improper re-use. Further, there is a need for a single-use

20 syringe which is only capable of reconstitution of a dried or lyophilized drug substances and not capable of injection into the human body.

### SUMMARY OF THE INVENTION

25 An operable single-use syringe comprises a barrel having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end having a distal wall with a tip extending distally therefrom having a passageway therethrough in fluid communication with the chamber. A plunger rod includes an elongate body portion defining a longitudinal axis, a proximal end and a distal end, a stopper at the distal end is slidably positioned in fluid-

30 tight engagement in the barrel. The stopper may be integrally formed as part of the plunger rod or be a separate base made of the same material as the plunger rod or another material such as a thermoplastic elastomer, natural rubber, synthetic rubber and the like. The body portion of the plunger rod extends outwardly from the open proximal end of the barrel and includes a compress at its distal end to facilitate movement of the plunger rod. The body

35 portion includes two parallel longitudinal slots wherein at least one of the slots includes a plurality of axially-spaced discontinuities, the discontinuities may take various shapes such as a saw tooth or ratchet-like structure. A locking element is positioned in the barrel between the elongate body portion of the plunger rod and the inside surface of the barrel. The locking

5 element has a proximal end, a distal end, a base and two leg segments in substantially parallel relationship extending from the base into each of the longitudinal slots. The locking element has one or more outwardly and distal end barbs and one or more outwardly and distally directed proximal end barbs. The barbs are for engaging the inside surface of the barrel to prevent proximal motion of the locking element with respect to the barrel. The legs include  
10 at least one deflectable, proximally positioned, resisting element for engaging the discontinuities on the plunger rod for moving the locking element in a distal direction along the inside surface of the barrel when the plunger rod is advanced in an additional direction and allowing proximal motion of the plunger rod with respect to locking element for filling the chamber.

15 The plunger rod may also include a proximal end barrier at its proximal end for establishing the most proximal position of the locking element on the plunger rod. The proximal end barrier may be configured to block access to the locking element through the open end of the barrel. The plunger rod may also include a distal end barrier at its distal end for establishing the distal-most position of the locking element on the plunger rod.

20 The single-use syringe may include a deflectable proximal resisting element on each leg member of the locking element. Each of the locking slots may include a plurality of axially-spaced discontinuities. The deflectable proximal resisting elements may face outwardly away from each other to engage the plurality of spaced discontinuities in each slot which face inwardly toward each other.

25 The single-use syringe may be configured so that the length of the locking element is less than 20% of the distance between the proximal end barrier and the distal end barrier.

The distal end of the locking element may include a distally directed cutting edge capable of cutting into and through the stopper if excessive proximally direct force is applied to the plunger rod to overcome the locking element and remove the plunger rod from the  
30 barrel.

The single-use syringe of the present invention may also include a needle assembly including a cannula having a proximal end, a distal end and a lumen therethrough. A hub having an open proximal end including a cavity therein, a distal end joined to the proximal end of the cannula so that the lumen is in fluid communication with the cavity. The tip of the  
35 barrel engages the hub so that the lumen of the cannula is in fluid communication with the chamber of the barrel.

The single-use syringe may also include an elongate cannula made of thermoplastic material. The cannula includes an inside surface, a proximal end, a distal end and a lumen

5 therethrough defining a longitudinal axis. The outside surface of the cannula at its proximal end has at least one discontinuity. The distal end of the cannula includes a stopper-piercing tip. The barrel is made of thermoplastic material wherein the tip of the barrel is formed in intimate contact around the proximal end of the cannula engaging the at least one discontinuity so that the lumen is in fluid communication with the chamber.

10 The tip of the cannula may include a closed distal end and at least one side aperture in fluid communication with the lumen. Alternatively, the tip of the cannula may include a planar surface at an obtuse angle with respect to the longitudinal axis of the cannula.

## 15 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of one embodiment of the single-use syringe of the present invention.

FIG. 2 is a perspective view of the plunger rod of the syringe of FIG. 1 as viewed from the proximal end.

20 FIG. 2A is a partially cross-sectioned view of the plunger rod of FIG. 2 taken along its longitudinal axis.

FIG. 3 is a perspective view of the plunger rod as viewed from the distal end.

FIG. 3A is a partially cross-sectioned view of the plunger rod of FIG. 3 taken along its longitudinal axis.

25 FIG. 4 is a perspective view of the locking element viewed from the proximal end.

FIG. 5 is a perspective view of the locking element viewed from the distal end.

FIG. 6 is a perspective view of the single-use syringe before use.

FIG. 7 is an enlarged partially cross-sectioned side-elevation view of the single-use syringe of FIG. 6.

30 FIG. 8 is a partially cross-sectioned side-elevation view of the single-use syringe after liquid has been drawn into the barrel chamber.

FIG. 9 is an enlarged partial side-elevation view of the syringe assembly of FIG. 8.

FIG. 10 is a partially cross-sectioned side-elevation view of the single-use syringe after discharge of liquid from the chamber of the barrel.

35 FIG. 11 is an enlarged partial side-elevation view of the syringe assembly of FIG. 10.

FIG. 12 is an enlarged partially cross-sectioned view, similar to FIG. 11, showing the locking element cutting through the stopper.

5           **FIG. 13** is an enlarged cross-sectional view of the syringe of **FIG. 6** taken along line 13-13.

**FIG. 14** is a partially cross-sectioned side-elevation view illustrating the single-use syringe being used to remove sterile liquid from a stoppered vial.

**FIG. 15** is a partially cross-sectioned side-elevation view showing the single-use  
10 syringe being used to withdraw sterile liquid from a glass ampoule.

**FIG. 16** is a side-elevation cross-sectional view of the distal end of the single-use syringe barrel showing an alternative cannula tip.

**FIGS. 17-19** illustrate a removable needle assembly for use with the single-use syringe.

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### **DETAILED DESCRIPTION OF THE INVENTION**

          There is shown in the drawings and will be described in detail herein preferred embodiments of the invention with the understanding that the present disclosure is to be considered exemplary of the principles of the invention and is not intended to limit the  
20 invention to the embodiments illustrated. The scope of the invention will be measured by the appended claims and their equivalents.

          For the purpose of the description of the present invention, the term "distal end" is intended to refer to the end furthest from the person holding the syringe, whereas the term "proximal end" is intended to refer to the end closest to the holder of the syringe.

25           An operable single-use syringe comprises a barrel **21** having an inside surface **22** defining a chamber **23** for retaining fluid, an open proximal end **25** and a distal end **26** having a distal wall **27** with a tip **28** extending distally therefrom having a passageway **29** therethrough in fluid communication with the chamber.

          A plunger rod **31** includes an elongate body portion **32** defining a longitudinal axis **34**, a proximal end **35** and a distal end **37**. A stopper **38** at the distal end of the plunger rod is  
30 slidably positioned in fluid-tight engagement in the barrel. The stopper may be a separate element connected to the body portion of the plunger rod. The separate stopper may be made of thermoplastic materials, thermoplastic elastomers, natural rubber, synthetic rubber and combinations thereof. The stopper in this embodiment is integrally formed with the elongate  
35 body portion and it is made of thermoplastic material such as polyethylene. The body portion of the plunger rod extends outwardly from the open proximal end of the barrel to facilitate moving the stopper in the barrel. The body portion includes two parallel longitudinal slots **39** and **40**. At least one of the slots includes a plurality of axially-spaced

5 discontinuities such as ratchet-like teeth 41 in slot 39. In this embodiment, longitudinal slot 40 also includes axially-spaced discontinuities in the form of a ratchet-like teeth 42. The teeth include distally-facing surfaces 44 and inclined surfaces 45. As will be explained hereinafter, the axially-spaced discontinuities can take a wide variety of shapes and forms all falling within the purview of the present invention with the ratchet-like teeth being merely  
10 representative of these various possibilities.

A locking element 51 is positioned in the barrel between the elongate body portion of the plunger rod and the inside surface of the barrel. The locking element includes a proximal end 52, a distal end 53, a base 55 and leg members 56 and 57 in substantially parallel relationship extending from the base into each of the longitudinal slots in the plunger rod. A  
15 locking element has at least one outwardly and distally directed distal end barb, and in this embodiment there are two distal end barbs 58 and 59 for engaging the inside surface of the barrel to prevent proximal motion of the locking element with respect to the barrel. The locking element also includes at least one outwardly and distally directed proximal end barb, and in this embodiment includes proximal end barbs 62 and 63 also for engaging the inside  
20 surface of the barrel to prevent proximal motion of the locking element with respect to the barrel. There should be at least one deflectable resisting element extending from one of the leg members. In this embodiment there are two deflectable resisting elements 64 and 65 for engaging the ratchet-like teeth on the plunger rod for moving the locking element in a distal direction along the inside surface of the barrel when the plunger rod is advanced in a distal  
25 direction and allowing proximal motion of the plunger rod with respect to the locking element when filling the chamber. In this embodiment, axially-spaced discontinuities in the form of ratchet-like teeth 41 and 42 face each other while deflectable resisting elements 64 and 65 face outwardly away from each other for engaging the discontinuities. Plunger rod 31 in this embodiment is symmetric along its longitudinal axis having longitudinal slots with  
30 discontinuities on two sides. This symmetric configuration is believed to improve manufacturability by reducing the angle the plunger must be rotated to align with a locking element positioned for insertion in the longitudinal slots of the plunger rod. With this two-sided configuration the maximum angle a plunger rod must be rotated to accept a locking element is 90° versus 180° for a non-symmetrical plunger rod having only the two  
35 longitudinal slots.

In this embodiment the plunger rod includes a distal end barrier 46 at the distal end of the body portion for establishing the distal-most position of the locking element on the plunger rod. In this embodiment, the stopper and the distal end barrier are integrally formed.

5 This embodiment also includes a proximal end barrier 47 at the proximal end of the plunger rod for establishing the most proximal position of the locking element on the plunger rod. The proximal end barrier is preferably large enough to block a substantial portion of the bore of the barrel for blocking access to the locking element through the open proximal end of the barrel. This structural feature will frustrate attempts to use small tools to defeat the locking  
10 element and improperly re-use the syringe. A proximal end barrier that is large enough to block direct visual contact with the locking element through the open proximal end of the barrel should be large enough to block access to the locking element. Also, the channel-shaped locking element is supported and shielded from tampering by relatively large sidewalls 49 on the plunger rod. Further, the substantial structure of the plunger rod  
15 surrounding the locking element supports the locking element and helps it resist attempts to overcome the locking element by improperly twisting the plunger rod because rotation of the plunger rod drives the distal and proximal end barbs into the inside surface of the barrel further enhancing the grip of the locking element to the barrel. Also, connection 48 holding thumb press 50 on proximal end of elongate body portion 32 can be made frangible by  
20 structure and/or material so that excessive twisting or tension forces applied to the thumb press will cause it to disconnect from the remainder of the plunger rod to provide further resistance to improper tampering. These structural and functional improvements are important aspects of the present invention.

As best seen in Figs. 7 and 8 the maximum stroke of the plunger rod, and therefore  
25 the maximum volume the syringe can deliver, is a function of distance A between distal end barrier 46 and proximal end barrier 47 minus the axial length B of the locking element. The channel-shaped configuration of locking element 51 and the support provided by the structure surrounding the longitudinal slots in the plunger rod allow locking element length B to be less than some other prior art locking elements while still being strong enough to prevent re-  
30 use. Accordingly, all things being equal, short locking element 51 will allow more volume to be delivered from the syringe. The locking element and plunger rod of the present invention has been configured to fit an available 5ml syringe barrel and still allow the delivery of a full 5ml dose. Some prior art devices yield less than half the volume that the syringe barrel is capable of delivering in a non-single-use configuration. Using the structure of the present  
35 invention results in a more cost-effective single-use syringe structure therefore making more syringes available for mass immunization in a fixed budget program. It is preferred that axial length B of the locking element be less than 20% of the distance A between the distal end barrier and the proximal end barrier. As shown in Figs. 1, 6 and 7, the locking element is



5 positioned in its distal-most position allowing for the maximum delivery volume. However, the delivery volume for the syringe can be reduced by initially positioning the locking element distally from the proximal barrier.

As will be explained in more detail hereinafter, the single-use syringe of the present invention can be used in conjunction with a removable needle assembly, a permanently  
10 attached needle for injection or a plastic cannula suitable for reconstitution and not for human injection. In this embodiment the single-use syringe is illustrated with a thermoplastic cannula to function as a single-use reconstitution syringe assembly. In particular, cannula 71 preferably made of thermoplastic material, includes an outside surface 72, a proximal end 73, a distal end 75 and a lumen 77 therethrough defining a longitudinal axis 78. Outside surface  
15 72 at the proximal end of the cannula includes at least one discontinuity. In this embodiment the at least one discontinuity includes annular grooves 81 and annular projections 82.

The distal end of the cannula includes piercing tip 83. The piercing tip is much less sharp than the tip of a metal hypodermic needle, but still sharp enough to pierce the elastomeric stopper of a medication vial. The cannula at the distal end is much larger than a  
20 hypodermic needle intended for injection. In this embodiment, the distal end of the cannula has an outside diameter of at least 2mm (0.08 inch). The combination of the large diameter distal end of the cannula and the relatively blunt piercing tip results in a cannula that is unsuitable for injection and much less likely to cause accidental skin piercing which could result in injury or transfer of disease. The term "piercing tip" as used herein is intended to  
25 encompass the tips of larger than injection needle diameter being configured to pierce elastomeric septums of injection vials and not human skin under normal use. The cannula includes the proximal portion having a diameter larger than the diameter of the distal portion. The diameter of the proximal end is equal or greater than about 2.5mm (0.1 inch). The increased proximal portion diameter substantially strengthens the cannula when bending forces are applied without, as will be explained hereinafter, interfering with the ability to  
30 function properly.

In this embodiment, the distal end of the cannula at the piercing tip is closed and includes at least one side aperture 84 in fluid communication with lumen 77.

Piercing tips within the purview of the present invention can include other  
35 configurations. Fig. 16 illustrates an alternative embodiment wherein cannula 171 includes an outside surface 172, a proximal end 173, a distal end 175 and a lumen 177 therethrough defining longitudinal axis 178. A piercing tip 183 at the distal end of the cannula has an

5 outside diameter of at least 2mm (0.08 inch). The piercing tip has a generally planar surface  
184 positioned at an obtuse angle A with respect to longitudinal axis 128.

The syringe barrel is made of thermoplastic material and tip 28 is formed in intimate  
contact around proximal end 73 of the cannula engaging the annular grooves and projections  
so that lumen 77 is in fluid communication with chamber 23. Cannula 71 preferably projects  
10 distally from the distal wall of the barrel for a distance of at least 23mm (0.9 inch). In this  
preferred embodiment cannula 21 extends at least 23mm (0.9 inch) beyond the distal end of  
tip 28. The thermoplastic material of the cannula has a higher flexural modulus than the  
thermoplastic material of the barrel. The flexural modulus of the cannula material is at least  
50% higher than the flexural modulus of the barrel material. In this embodiment, the barrel is  
15 preferably formed of polypropylene and the cannula is preferably made of polycarbonate.

In the prior art, short hypodermic needle assemblies and short cannula-like spikes are  
used to withdraw liquid from a stoppered vial. Because these elements are removable, the  
syringe assembly used in the procedure can be subsequently improperly used with a needle  
for injecting substances into a person. In the case of a hypodermic needle being used to  
20 access the vial, the needle can also be improperly used if not properly disposed. The single-  
use syringe of the present embodiment eliminates these problems by providing an integral  
cannula and syringe barrel wherein the cannula has a large piercing tip not suitable for  
injecting substances into people. Further, it is easier to dispose of since it does not have any  
metal components. However, an integrally formed barrel and cannula having a short cannula  
25 would not be suitable for drawing liquid from a glass ampoule since the ampoule cannot be  
inverted without spilling the liquid and the cannula must be long enough to reach to the  
bottom of the ampoule. For these applications, a long hypodermic needle is used. This  
combination results in the same problems as having a potentially re-usable needle assembly  
and syringe barrel reusable for human injection as previously described. Further, a long  
30 plastic cannula made of commonly used plastics for these applications, such as  
polypropylene, may bend or become damaged if it were used in an attempt to pierce a  
stoppered vial. This is due to the long length of the cannula which renders it generally  
undesirable for piecing vials. It is an important aspect of the present invention that all of the  
above-mentioned problems are overcome by providing a syringe assembly having  
35 permanently attached cannula with a relatively large piecing tip which is not suitable for  
human injection. Further, the cannula is long enough to access vials yet strong enough to  
piece vial stoppers to effectively withdraw liquid from a vial. Also, disposal is simplified  
because there are no metal components in the syringe assembly. The issue of strength is

5 addressed by forming the cannula of a substantially more rigid material than the barrel. Also  
when the stopper is a rigid element, as in the preferred embodiment, the barrel must be  
flexible enough to provide a fluid-tight seal around the periphery of the stopper. The more  
rigid material used in the cannula could not be used in the barrel because the barrel would not  
have the necessary flexibility to provide an efficacious seal around the stopper and still allow  
10 the plunger rod to move with respect to the barrel when reasonable forces are applied. The  
syringe assembly of the present invention overcomes the deficiencies of the prior art by  
providing a reconstitution syringe having a rigid plastic cannula with a tip not suitable for  
human injection which can adequately access stoppered vials and glass ampoules to  
reconstitute medication and subsequently to be easily destroyed and not be a danger for drug  
15 is-use.

Single-use syringe 20 is assembled by placing locking element 51 on the plunger rod  
so that leg members 56 and 57 are in longitudinal slots 39 and 40 and then plunger rod 31  
with locking element 51 is inserted in the proximal end of the barrel. The position of the  
locking element on the plunger rod when the syringe is assembled determines the maximum  
20 dose the syringe assembly can deliver. Single-use syringe 20 as assembled and ready to use  
is illustrated in Figs. 6 and 7. Deflectable resilient elements 64 and 65 on the locking element  
work in conjunction with ratchet-like teeth 43 to allow the plunger rod to move in the  
proximal direction with respect to the locking element to draw liquid into the barrel as  
illustrated in Figs. 8 and 9. The locking element cannot move in a proximal direction due to  
25 the engagement of distal end barbs 58 and 59 and proximal end barbs 62 and 63 with the  
inside surface of the barrel. However, the ratchet-like teeth working in conjunction with the  
deflectable resisting elements allow the plunger to move proximally with respect to the  
locking element to fill a syringe barrel. To discharge liquid from the chamber of the barrel,  
force is applied to the thumb press of the plunger rod to move the plunger rod in a distal  
30 direction with respect to the barrel. As plunger rod 31 moves distally in barrel 21 the  
interaction of the ratchet-like teeth and deflectable resilient elements on the locking element  
cause the locking element to move distally in the barrel along with the plunger rod until the  
stopper contacts distal wall 27 of the barrel. At this point the plunger rod can no longer move  
distally within the barrel and it can no longer move proximally within the barrel because the  
35 distal end barbs 58 and 59 and the proximal end barbs 62 and 63 are engaging the barrel and  
preventing withdrawal of the plunger rod from the barrel.

Locking element 51 further includes distally directed cutting edge 67 which provides  
further protection against improper re-use of the single-use syringe. By applying excessive

5     proximally-directed force to the plunger rod, as illustrated in Fig. 12, the stopper will be pulled proximally with respect to the cutting edge causing the cutting edge to cut through the stopper or to severely damage the stopper so that the stopper is cut and disfigured and can no longer function effectively to discharge liquid from the barrel.

10     The present embodiment of the single-use syringe having a thermoplastic cannula with a piercing tip can be used to reconstitute medications wherein the liquid component is contained in a stoppered vial. As illustrated in Fig. 14, stoppered vial 90 includes a vial 91, a pierceable stopper 92, a sheet metal closure 93 for holding the stopper in place on the vial and a quantity of sterile liquid 94. The liquid is drawn into the syringe using known clinically accepted methods which include piercing the stopper of the vial with piercing tip 83 of  
15     cannula 71 and moving the plunger in a proximal direction with respect to the barrel to draw liquid into the chamber of the barrel while the vial is inverted so that the short length of cannula can access all of the liquid in the vial. The plunger can draw liquid into the barrel until distal end barrier 46 contacts locking element 51. Syringe 20 with integral cannula 71 is then withdrawn from the stoppered vial and used to transfer liquid into the dried or  
20     lyophilized medication, such as vaccine, for subsequent injection into the patient. The vaccine may also be contained in a stoppered vial. If so, the integral cannula of the syringe assembly can again be used to pierce the stopper and force the water into the medication containing vial for subsequent injection into a patient.

25     Fig. 15 illustrates syringe assembly 20 being used to withdraw sterile liquid from a glass ampoule 95 containing sterile liquid 94. For this application, the cannula must be small enough to enter the severed neck of the ampoule and long enough to access sterile liquid 94 at the bottom of the ampoule. It is anticipated that a cannula with an effective length of 23mm (0.9 inch) to 38mm (1.5 inch) will be able to work with the majority of ampoules believed to be available. It is preferred that the effective length be measured from the distal  
30     end of the barrel tip to the distal end of the cannula since it is anticipated that a barrel tip of adequate strength will be much larger than the cannula and not suitable to enter some ampoules. However, if the barrel tip is small enough to fit into the ampoule, the effective length can be measured from the distal wall of the barrel.

35     The flexural modulus of the cannula material, measured in units Mpa is at least 50% greater than the flexural modulus of the barrel material. Preferred materials for the barrel and the cannula are polypropylene and polycarbonate respectively. Polycarbonate, having a flexural modulus of about 2275 Mpa gives the cannula the substantial strength it needs to function properly and still be long enough to access the full depth of an ampoule and the

5 polypropylene, having a flexural modulus of about 1100 Mpa, provides a relatively flexible, less rigid, barrel that will provide an adequate seal for a thermoplastic stopper made of material such as polyethylene. Also, the shrinkage rate of polypropylene in the molding process is greater than the shrinkage rate of polycarbonate so that as the molded polypropylene which surrounds the proximal end of the polycarbonate cannula solidifies the  
10 barrel tip will shrink tightly around the polycarbonate needle to hold it even with more force than if the materials had similar shrinkage rates. Accordingly, even if the polycarbonate cannula is still in the process of solidifying injection molding of the barrel over the cannula is possible.

Referring to Figs. 17-19, the single-use syringe of the present invention can also be  
15 used with a removable needle assembly for reconstitution or injection and the like. Needle assembly 270 includes a cannula 271 having a proximal end 273, a distal end 275 and a lumen 277 therethrough, and a hub 276 having an open proximal end 279 including a cavity 280 therein. A distal end 285 of the hub is joined to the proximal end of the cannula so that the lumen of the cannula is in fluid communication with the cavity. Tip 28 of the barrel  
20 removably engages the hub of the needle assembly so that the lumen is in fluid communication with the barrel chamber. The distal tip of the cannula may be a stopper piercing tip as described hereinabove or a sharp bevel tip suitable for injection such as tip 283.

Referring to Fig. 20, the single-use syringe of the present invention can also be used  
25 with a permanently attached cannula 371 having a proximal end 373, a distal end 375 and a lumen therethrough. Barrel 321 includes a tip 328 with a passageway 329 therethrough. The proximal end of the cannula is positioned in the passageway and held permanently to the barrel tip through the use of adhesive 330. There are numerous ways to permanently attach a cannula to a barrel tip such as a press-fit, crimping the barrel tip, and the like, all of which are  
30 within the purview of the present invention with the adhesive connection illustrated being merely representative of these many possibilities. The distal tip of the cannula may be a stopper piercing tip as described hereinabove or a sharp bevel tip suitable for injection such as tip 383 as illustrated in Fig. 20.

35

5

## WHAT IS CLAIMED IS:

## 1. An operable single-use syringe comprising:

10 a barrel having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end having a distal wall with a tip extending distally therefrom having a passageway therethrough in fluid communication with said chamber;

a plunger rod including an elongate body portion defining a longitudinal axis, a proximal end and a distal end, a stopper at said distal end slidably positioned in fluid-tight engagement in said barrel, said body portion extending outwardly from said open proximal

15 end of said barrel, said body portion including two parallel longitudinal slots, at least one of said slots including a plurality of axially spaced discontinuities;

a locking element positioned in said barrel between said elongate body portion of said plunger rod and said inside surface of said barrel, said locking element having a proximal end, a distal end, a base and two leg members in substantially parallel relationship extending

20 from said base into each of said longitudinal slots, said locking element having an outwardly and distally directed distal end barb and an outwardly and distally directed proximal end barb for engaging said inside surface of said barrel to prevent proximal motion of said locking element with respect to said barrel, said legs including at least one deflectable resisting element for engaging said discontinuities on said plunger rod for moving said locking

25 element in a distal direction along said inside surface when said plunger rod is advanced in a distal direction and allowing proximal motion of said plunger rod with respect to said locking element for filling said chamber.

30 2. The single-use syringe of Claim 1 wherein locking element includes a second outwardly and distally directed distal end barb.

3. The single-use syringe of Claim 1 wherein said locking element includes a second outwardly and distally directed proximal end barb.

35 4. The single-use syringe of Claim 1 further including a proximal end barrier at said proximal end of said body portion of said plunger rod for establishing the most proximal position of said locking element on said plunger rod.

5           5. The single-use syringe of Claim 4 wherein said proximal end barrier blocks access to said locking element through said open proximal end of said barrel.

6. The single-use syringe of Claim 4 further including a distal end barrier at said distal end of said body portion of said plunger rod establishing the distal-most position of  
10 said locking element on said plunger rod.

7. The single-use syringe of claim 1 wherein said at least one deflectable proximal resisting element includes a deflectable resisting element on each leg member.

15           8. The single-use syringe of Claim 7 wherein each of said longitudinal slots includes a plurality of axially spaced discontinuities.

9. The single-use syringe of Claim 8 wherein said deflectable resisting elements face outwardly away from each other and said plurality of axially spaced discontinuities in  
20 each slot face inwardly toward each other.

10. The single-use syringe of Claim 6 wherein the axial length of said locking element is less than 20% of the distance between said proximal end barrier and said distal end barrier.  
25

11. The single-use syringe of Claim 1 wherein said locking element includes a distally directed cutting edge at its distal end capable of cutting into said stopper if excessive proximally-directed force is applied to said plunger rod to overcome said locking element and remove said plunger rod from said barrel.  
30

12. The single-use syringe of Claim 1 wherein said plunger rod and said stopper are integrally formed of the same material.

13. The single-use syringe of Claim 1 wherein said locking element is made of sheet  
35 metal.

14. The single-use syringe of Claim 1 further comprising a needle assembly including a cannula having a proximal end, a distal end and a lumen therethrough, a hub

- 5     having an open proximal end including a cavity therein, a distal end joined to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said tip of said barrel engaging said hub so that said lumen is in fluid communication with said chamber.

10         15. The single-use syringe of claim 1 further comprising a cannula having a proximal end, a distal end and a lumen therethrough wherein said proximal end of said cannula is connected to said tip of said barrel so that said lumen is in fluid communication with said passageway.

15         16. The single-use syringe of Claim 1 further comprising:  
an elongate cannula made of thermoplastic material, said cannula having an outside surface, a proximal end, a distal end and a lumen therethrough defining a longitudinal axis, said outside surface at said proximal end including at least one discontinuity, said distal end having a stopper piercing tip; and  
said barrel being made of thermoplastic material, said tip of said barrel being formed  
20     in intimate contact around said proximal end of said cannula engaging said at least one discontinuity so that said lumen is in fluid communication with said chamber, said cannula projecting distally from said distal wall.

25         17. The single-use syringe of Claim 16 wherein said tip of said cannula includes a closed distal end and at least one side aperture in fluid communication with said lumen.

18. The single-use syringe of Claim 16 wherein said tip of said cannula includes a planar surface and at an angle with respect to said longitudinal axis.

30         19. The single-use syringe of Claim 16 wherein said cannula projects distally from said distal wall of said barrel for a distance of at least 23mm (0.9 inch).

20. The single-use syringe of Claim 16 wherein the distal end of said cannula has an outside diameter of at least 2mm (0.08 inch).

35

21. The single-use syringe of Claim 16 wherein said proximal end of said cannula has an outside diameter of at least 2.5mm (0.1 inch).



5           22. The single-use syringe of Claim 16 wherein said thermoplastic material of said cannula has a flexural modulus of at least 50% greater than the flexural modulus of said thermoplastic material of said barrel.

10           23. The single-use syringe of Claim 16 wherein said cannula is made of polycarbonate.

          24. The syringe assembly of Claim 16 wherein said barrel is made of polypropylene.

          25. An operable single-use syringe comprising:  
15           an elongate cannula made of thermoplastic material, said cannula having an outside surface, a proximal end, a distal end and a lumen therethrough defining a longitudinal axis, said outside surface at said proximal end including at least one discontinuity, said distal end having a stopper piercing tip;  
          a thermoplastic barrel having an inside surface defining a chamber for retaining fluid,  
20           an open proximal end and a distal end having a distal wall with a tip extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said tip being formed in intimate contact around the proximal end of said cannula engaging said at least one discontinuity so that said lumen is in fluid communication with said chamber, said cannula projecting distally from said distal wall for a distance of at least 23mm (0.9 inch),  
25           said thermoplastic material of said cannula having a higher flexural modulus than said thermoplastic material of said barrel;

          a plunger rod including an elongate body portion defining a longitudinal axis, a proximal end and a distal end, a stopper at said distal end slidably positioned in fluid-tight engagement in said barrel, said body portion extending outwardly from said open proximal  
30           end of said barrel, said body portion including two parallel longitudinal slots, each of said slots including a plurality of axially spaced discontinuities; and

          a locking element positioned in said barrel between said elongate body portion of said plunger rod and said inside surface of said barrel, said locking element having a proximal end, a distal end, a base and two leg members in substantially parallel relationship extending  
35           from said base into each of said longitudinal slots, said locking element having two outwardly and distally directed distal end barbs and two outwardly and distally directed proximal end barbs for engaging said inside surface of said barrel to prevent proximal motion of said locking element with respect to said barrel, said legs each including a deflectable

5 proximal resisting element for engaging said discontinuities on said longitudinal slots for moving said locking element in a distal direction along said inside surface when said plunger rod is advanced in a distal direction and allowing proximal motion of said plunger rod with respect to said locking element for drawing fluid into said chamber.

10 26. A single-use syringe of Claim 25 wherein further including a proximal end barrier at said proximal end of said body portion of said plunger rod establishing the most proximal position of said locking element on said plunger rod.

27. The single-use syringe of Claim 26 wherein said proximal end barrier blocks  
15 access to said locking element through said open proximal end of said barrel.

28. The single-use syringe of Claim 25 further including a distal end barrier at said distal end of said body portion of said plunger rod establishing the distal-most position of said locking element on said plunger rod.

20 29. The single-use syringe of Claim 25 wherein said locking element includes a distally directed cutting edge at its distal end capable of cutting into said stopper if excessive force is applied to said plunger rod to overcome said locking element and remove said plunger rod from said barrel.

25 30. The single-use syringe of Claim 25 wherein said thermoplastic material of said cannula has a flexural modulus of at least 50% greater than the flexural modulus of said thermoplastic material of said barrel.

30 31. The single-use syringe of Claim 25 wherein said plunger rod and said stopper are integrally formed of the same material.

32. The single-use syringe of Claim 25 wherein said locking element is made of sheet metal.

35 33. The single-use syringe of Claim 25 wherein the cannula is made of polycarbonate.

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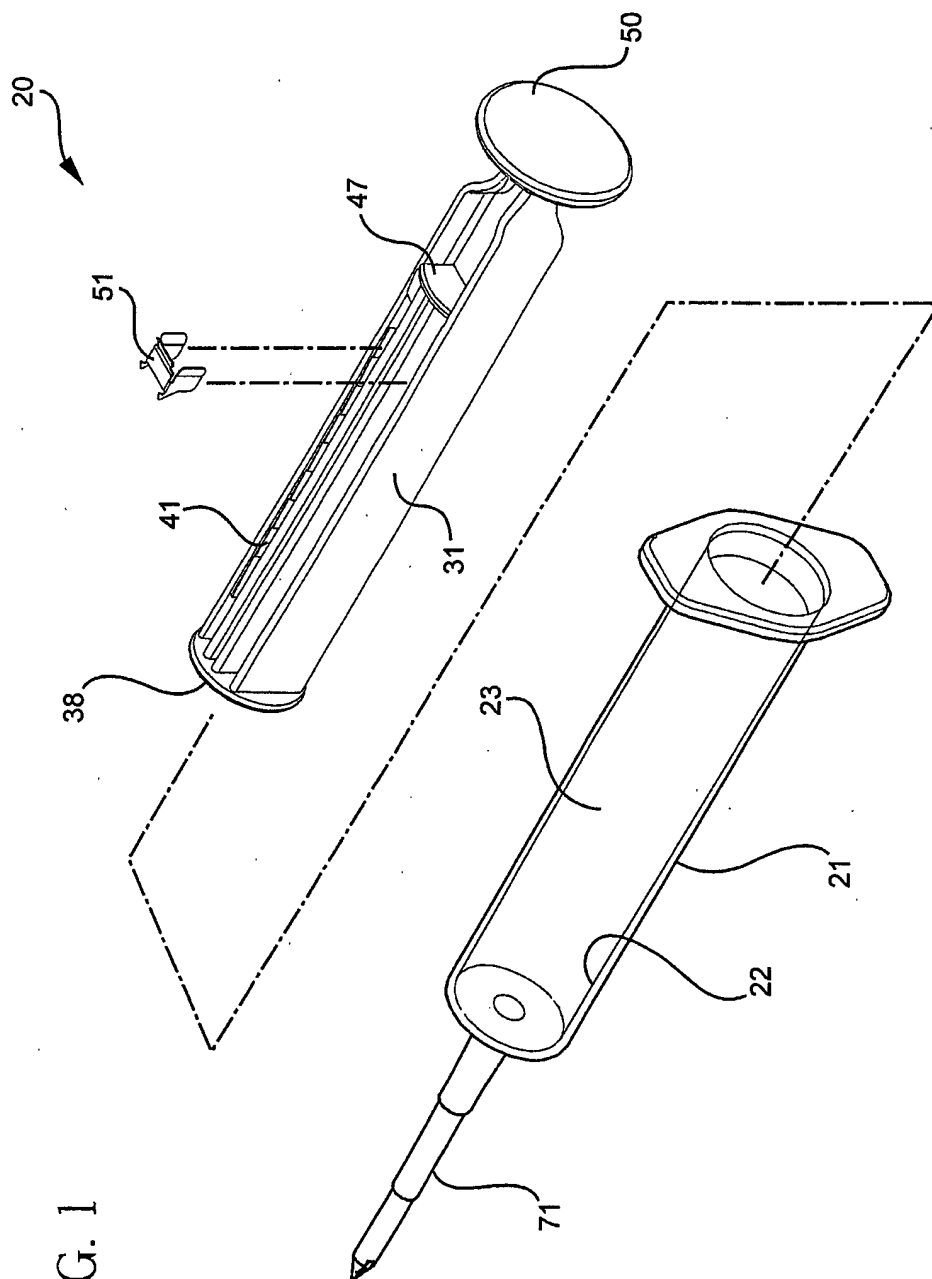
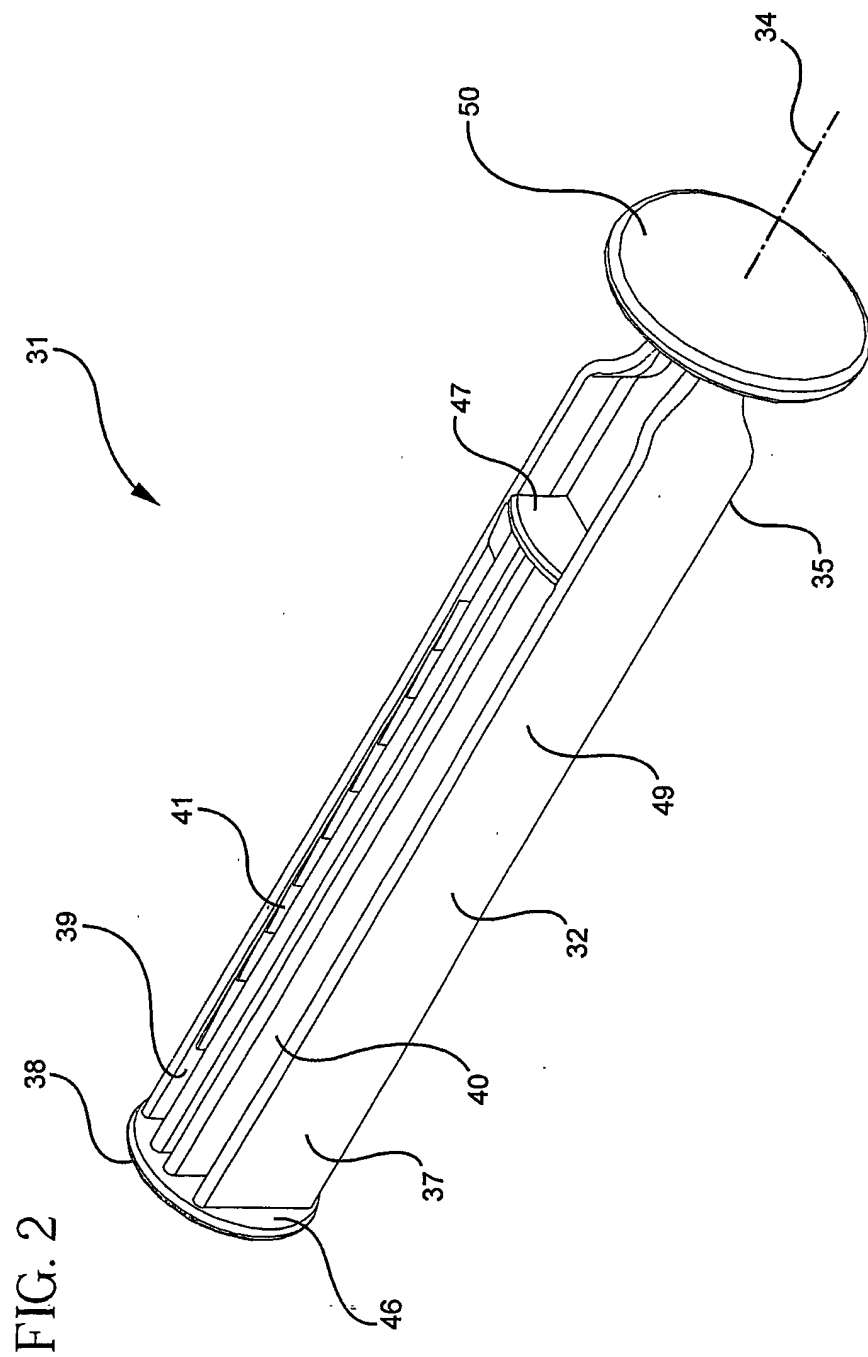


FIG. 1

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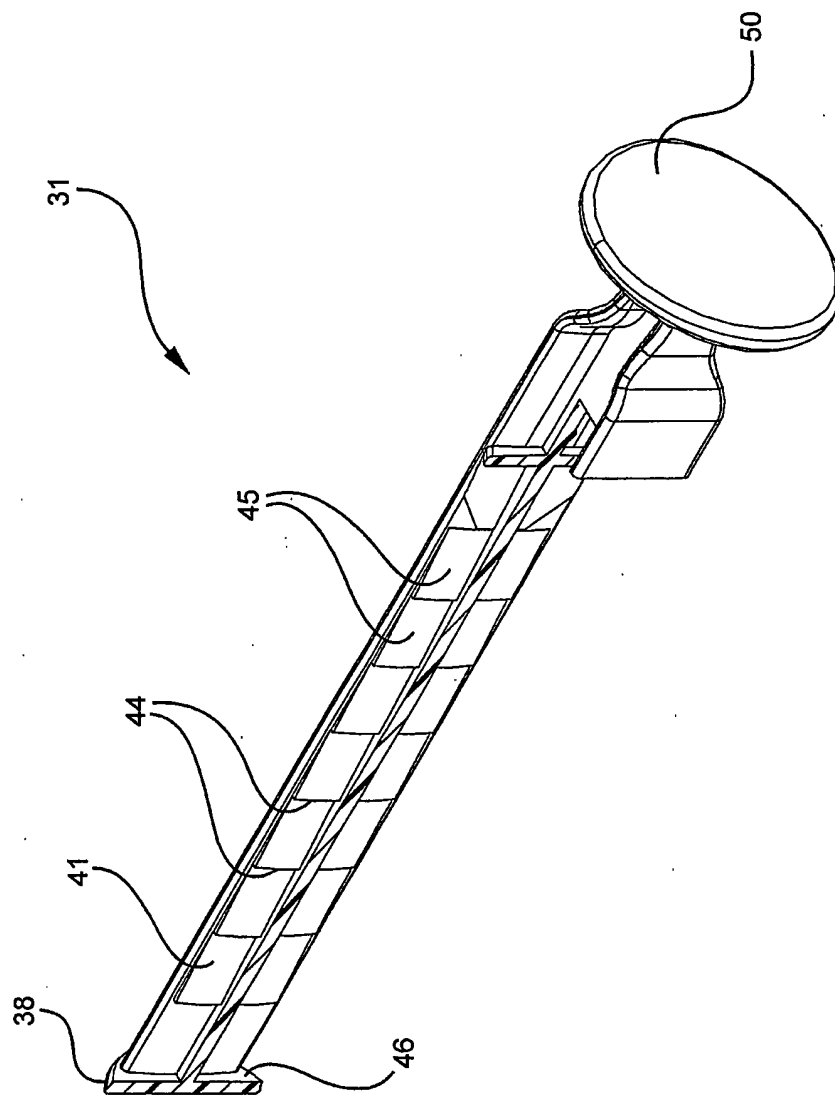
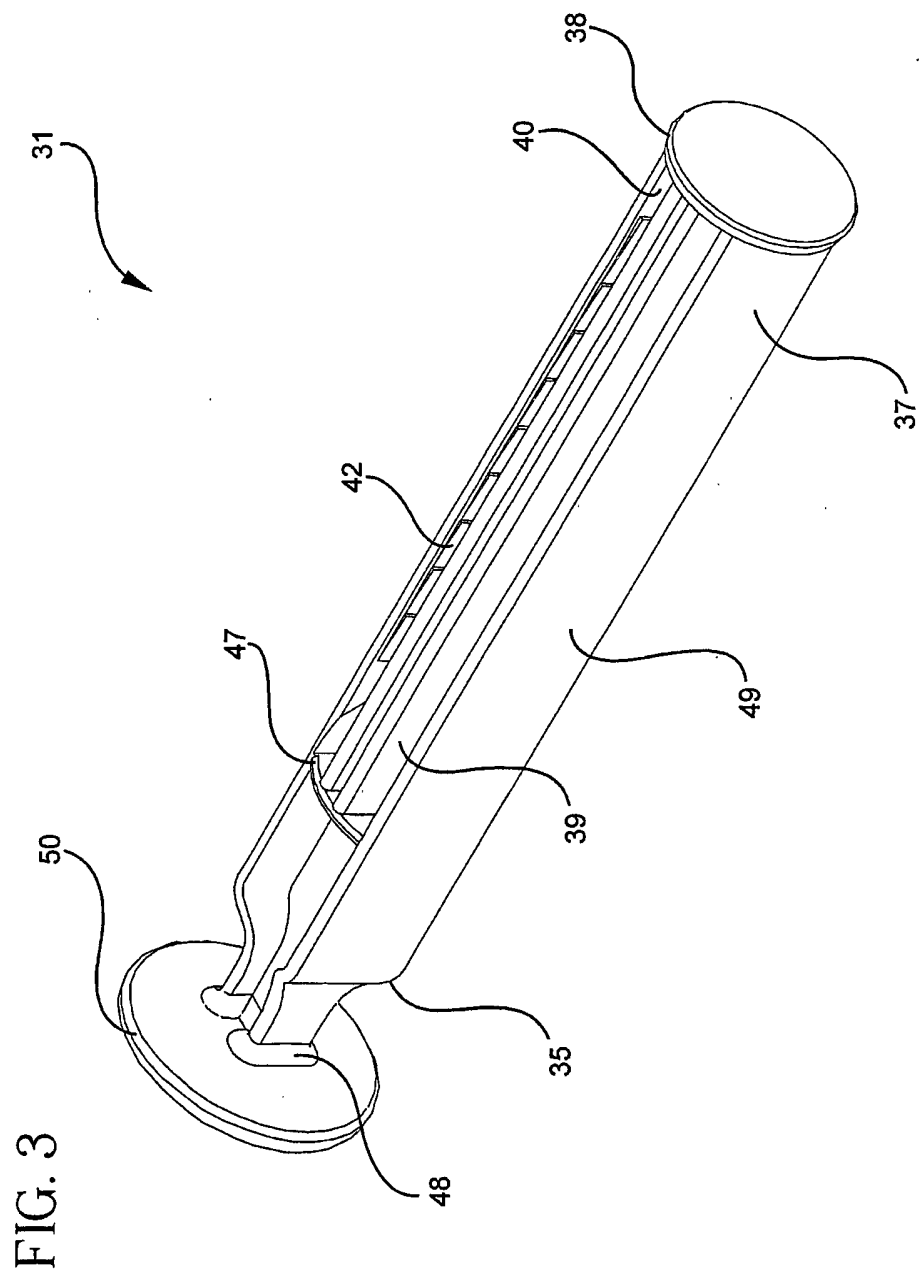
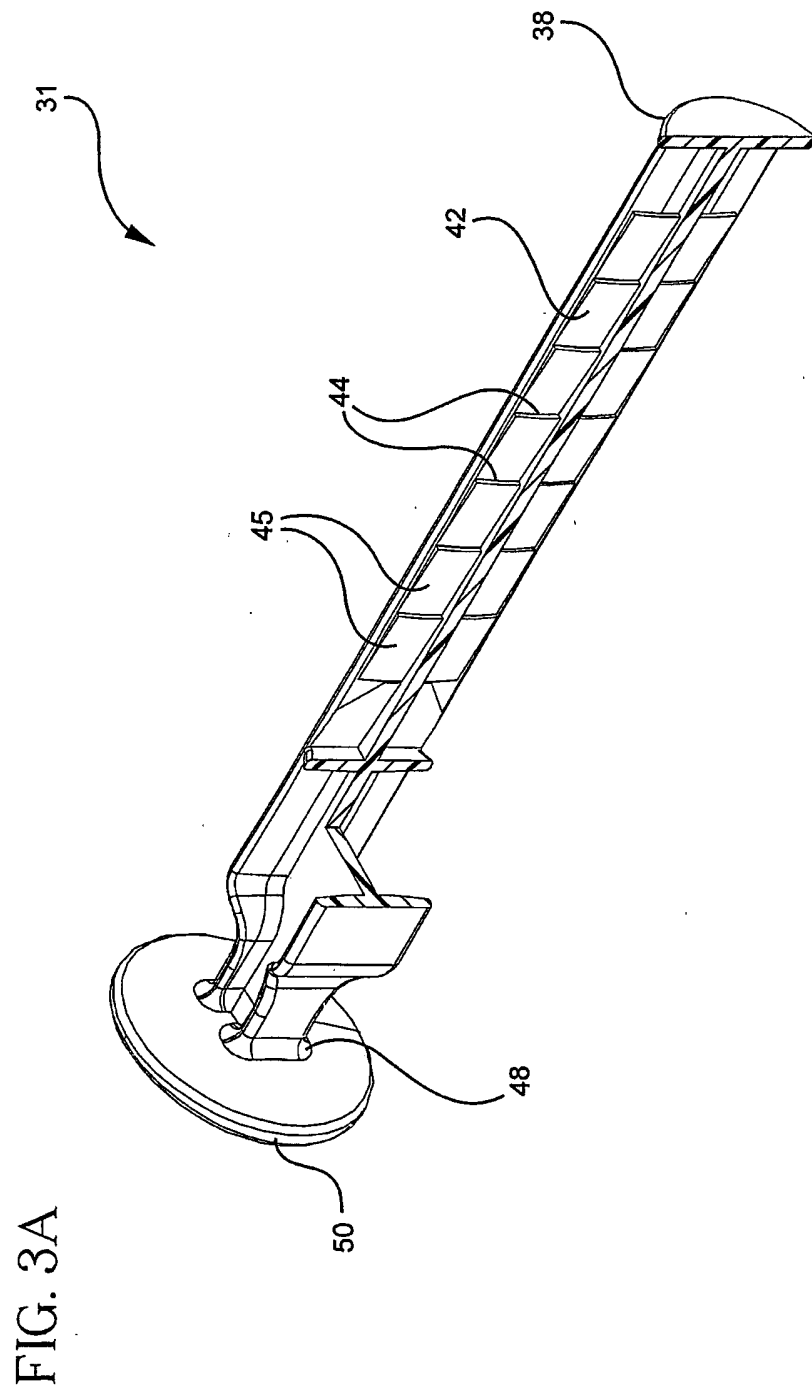


FIG. 2A

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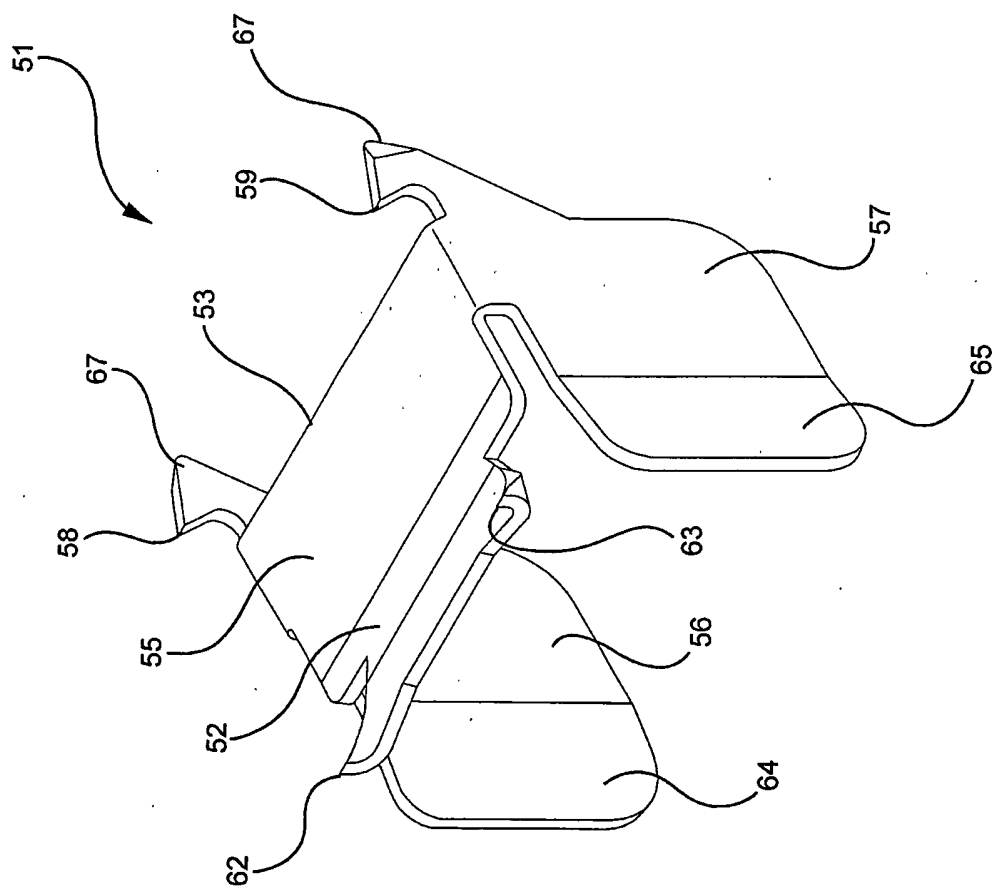
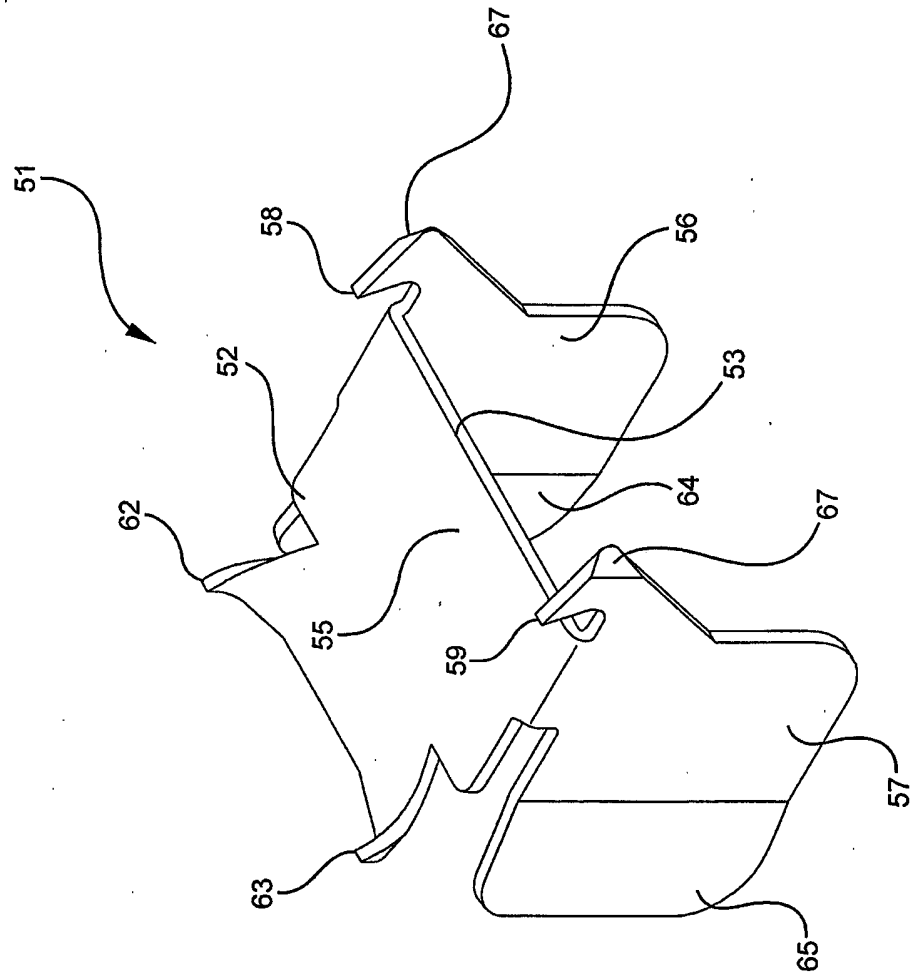


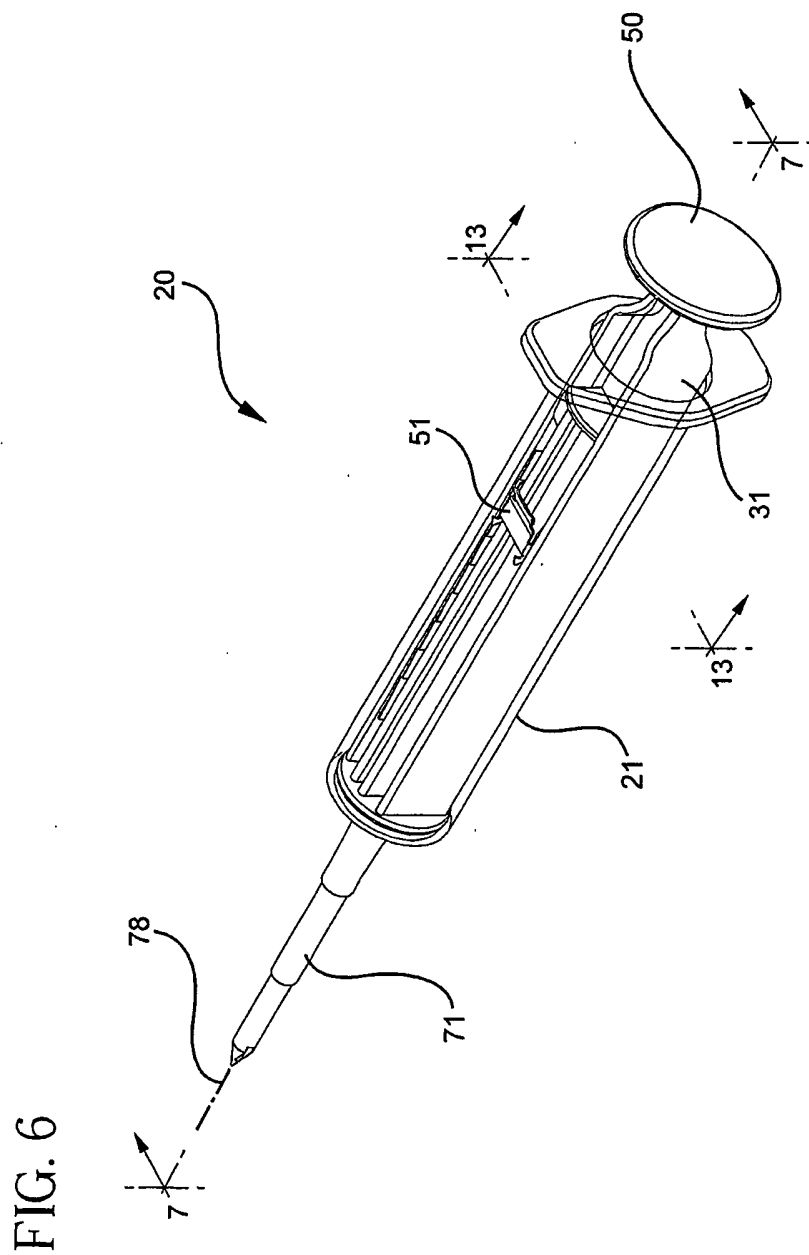
FIG. 4



FIG. 5

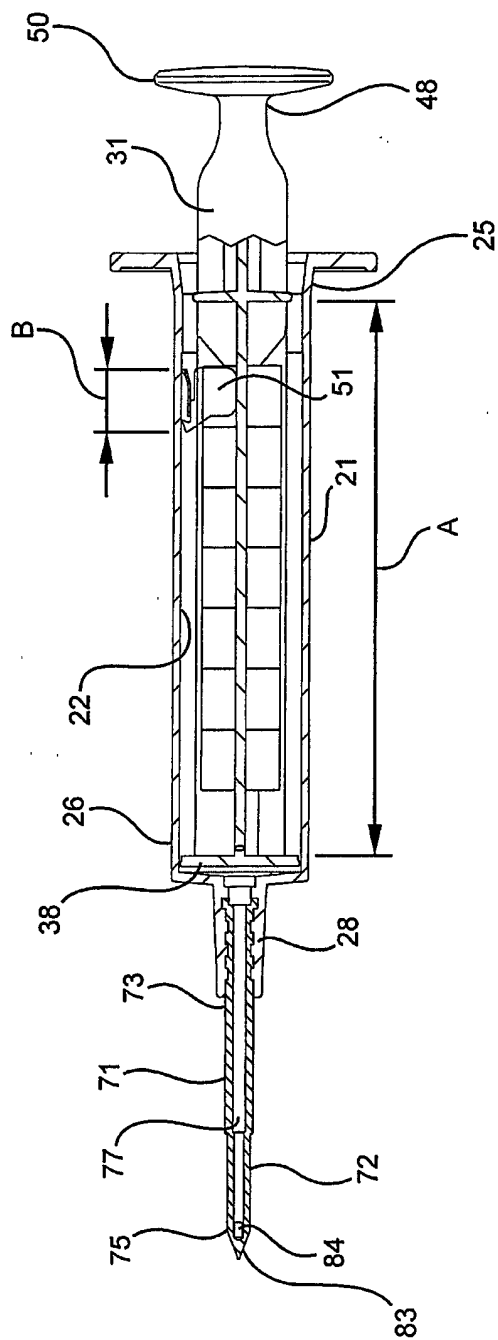


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FIG. 7



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FIG. 8

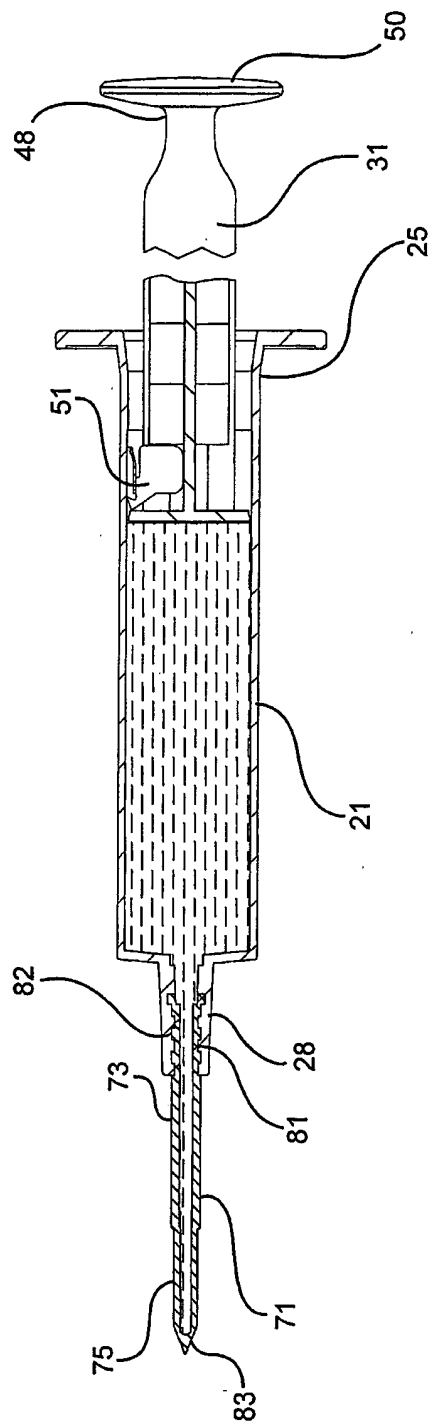
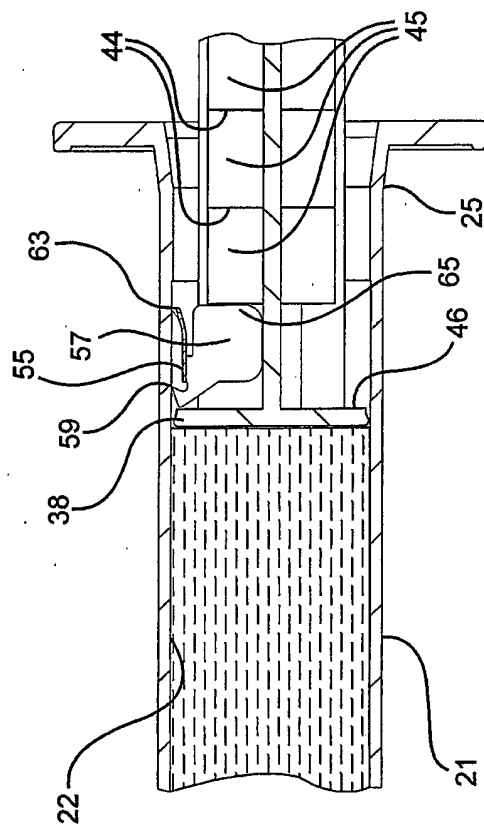


FIG. 9



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FIG. 10

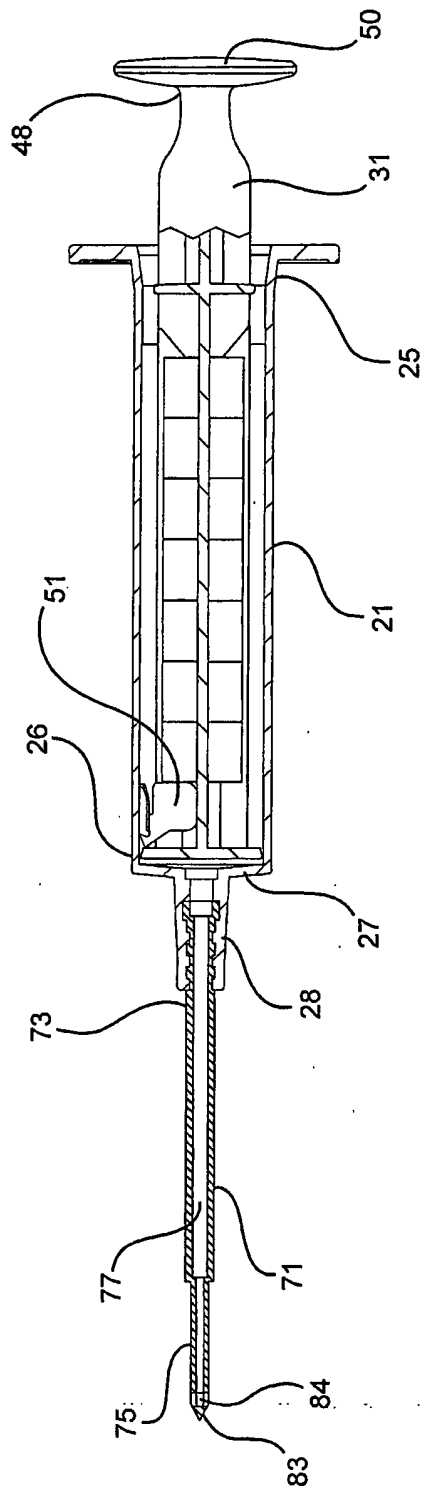
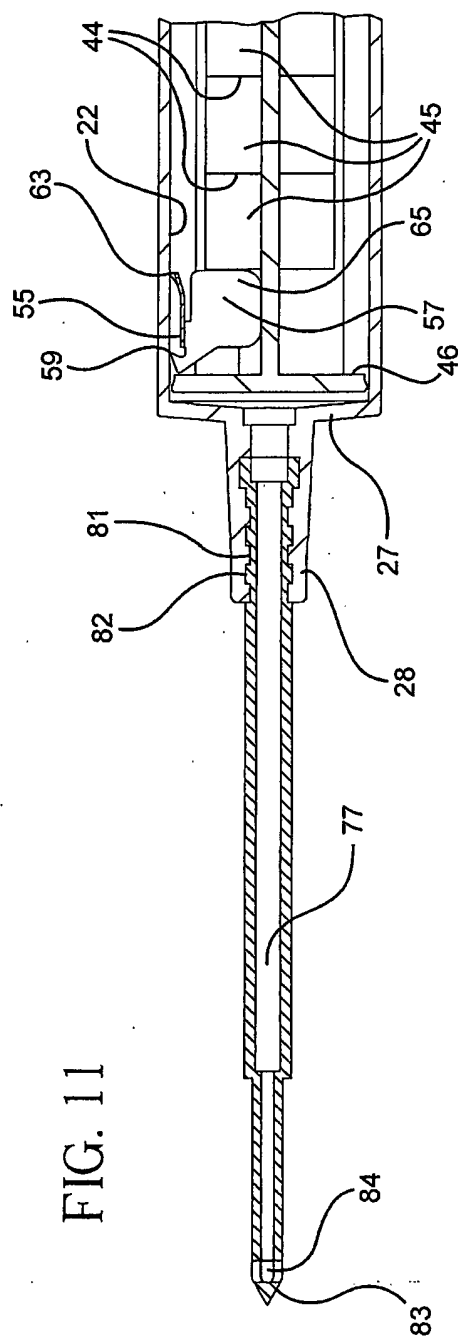


FIG. 11



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FIG. 12

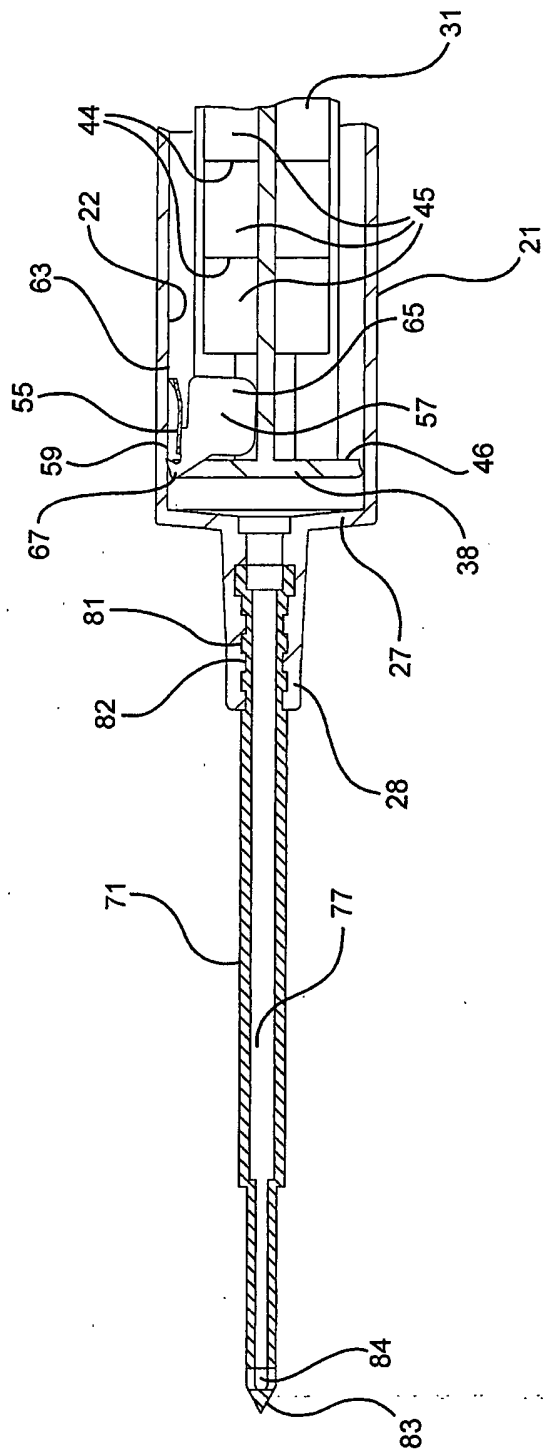
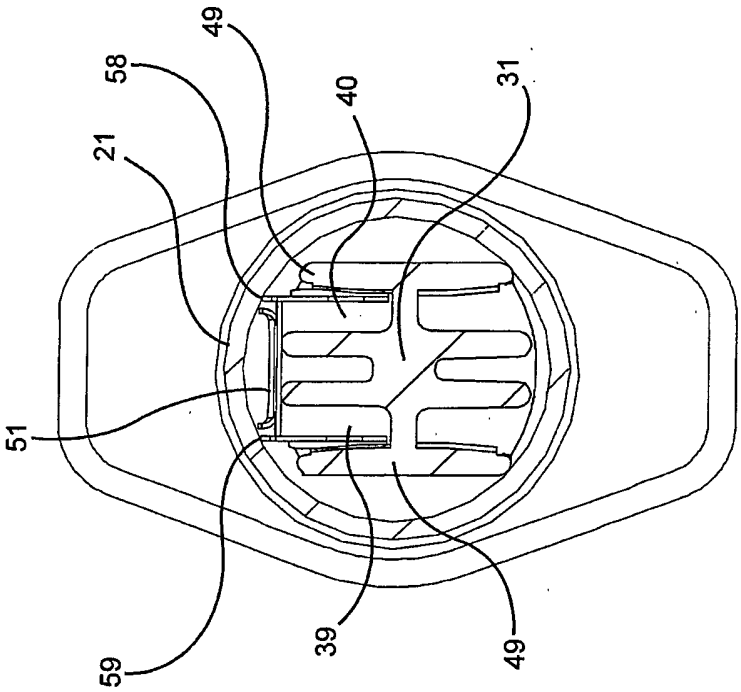


FIG. 13



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FIG. 14

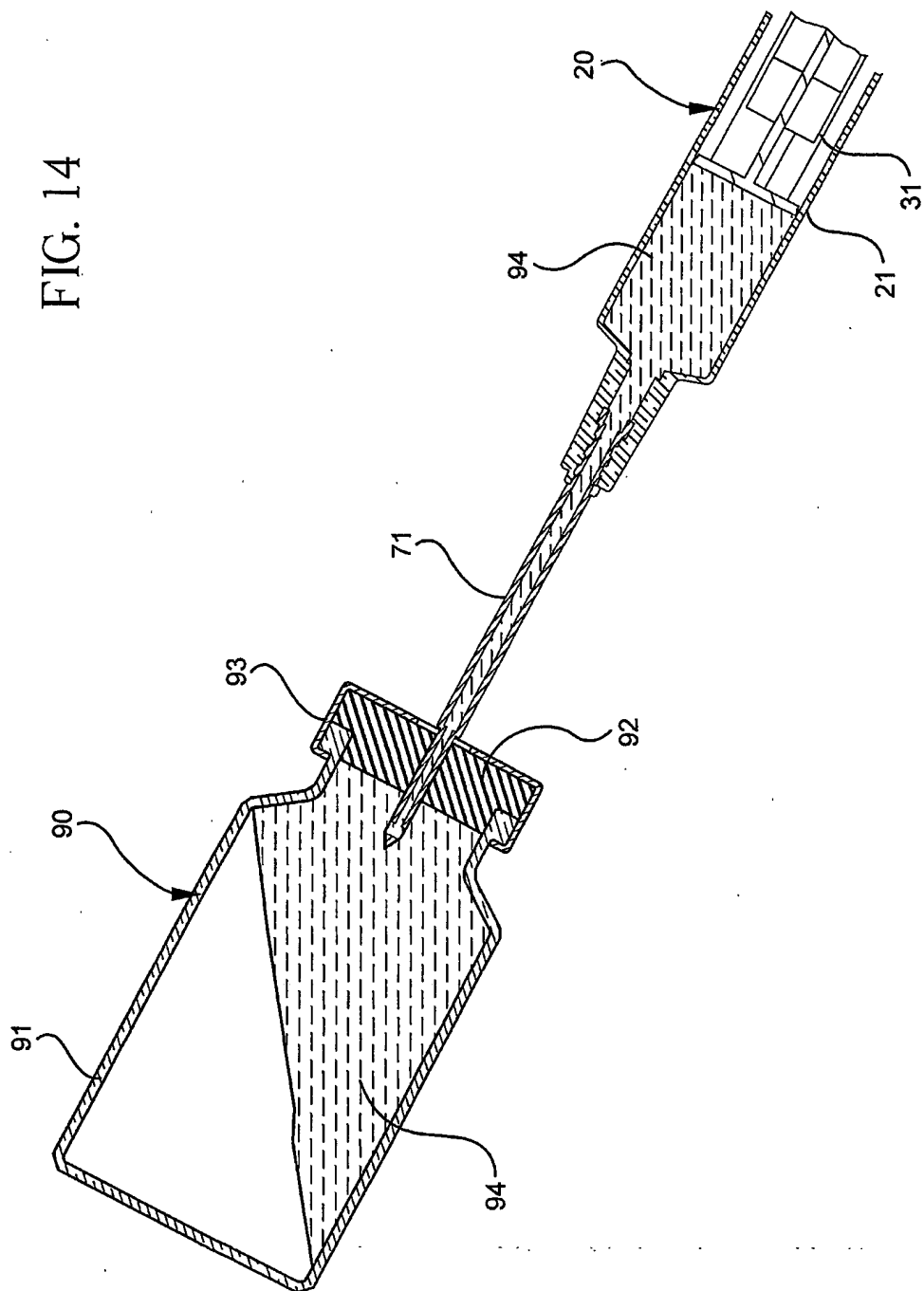
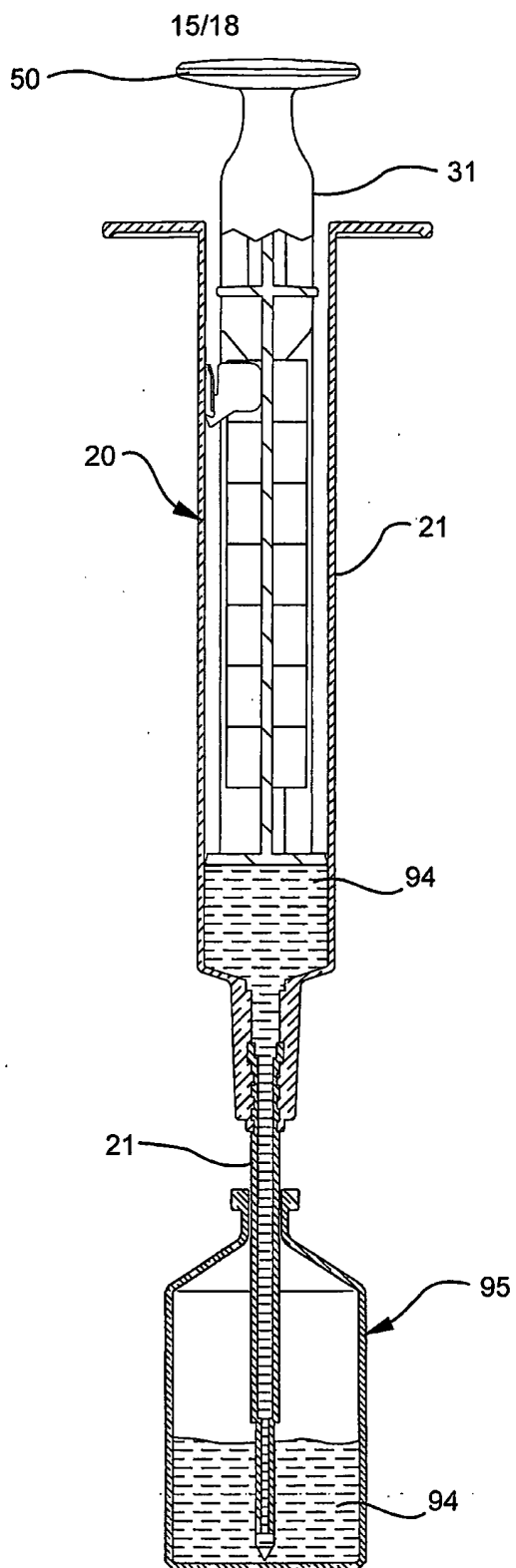


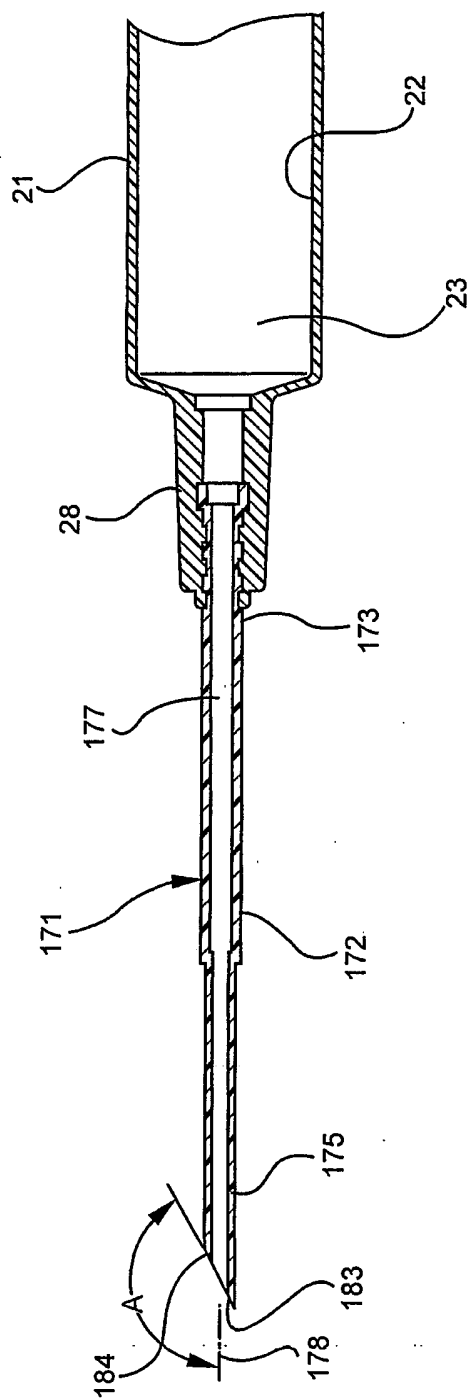


FIG. 15



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FIG. 16



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FIG. 17

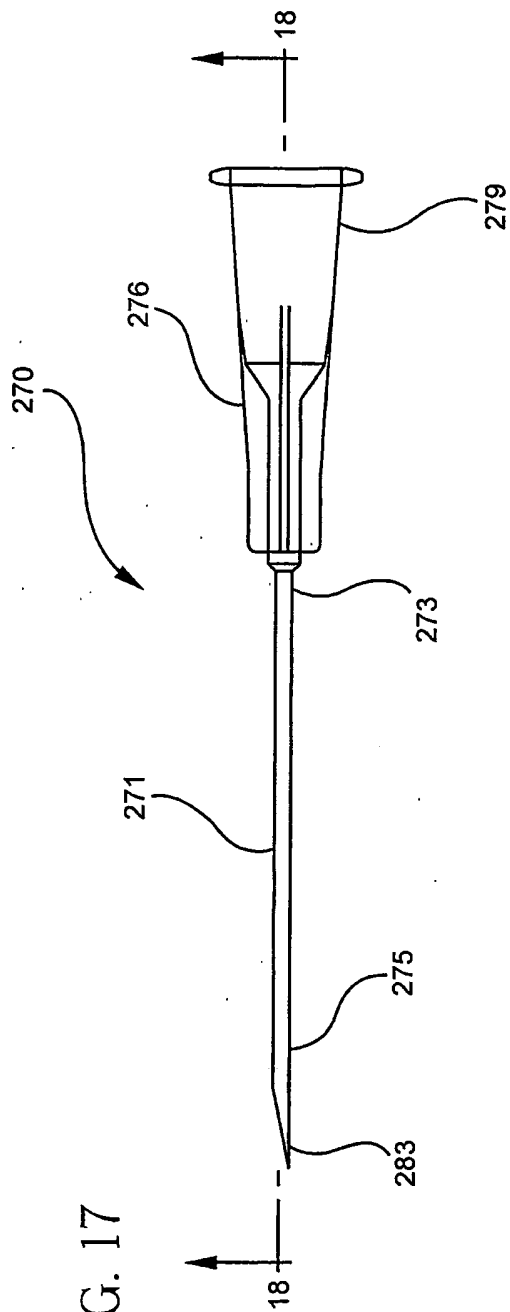
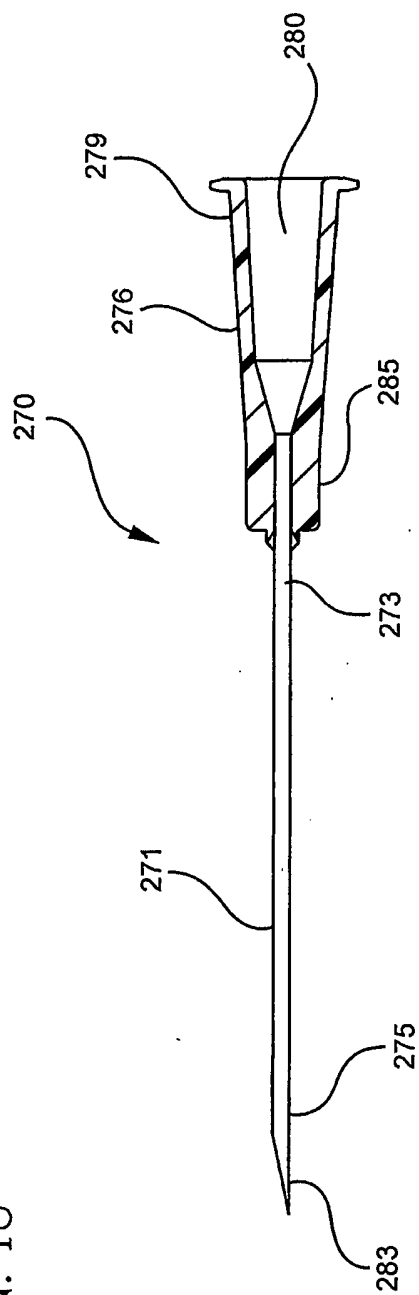
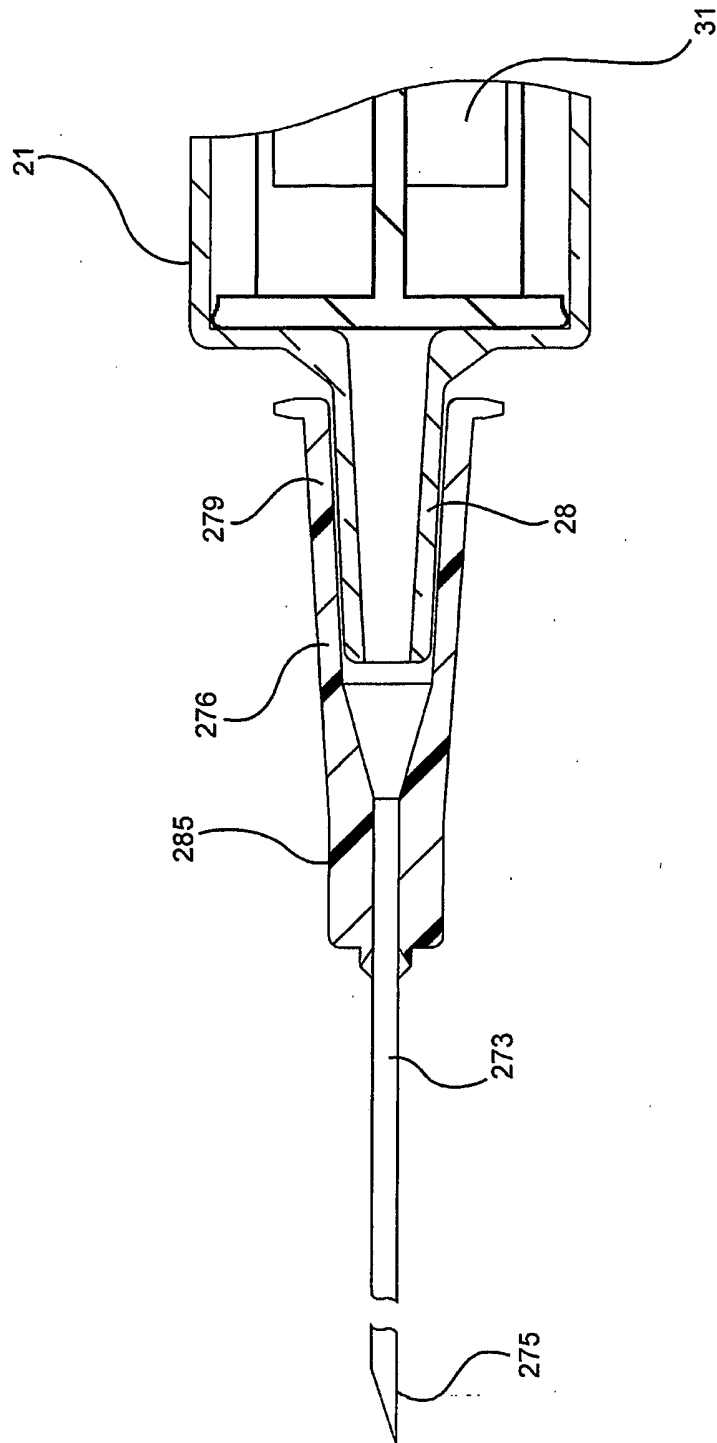


FIG. 18



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FIG. 19



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/022427

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2001/049506 A1 (SCHOENFELD JOEL ET AL) 6 December 2001 (2001-12-06) abstract paragraphs '0021! - '0026!; figures 1-7	1,25
A	WO 2004/028604 A (BECTON DICKINSON AND COMPANY) 8 April 2004 (2004-04-08) abstract; figures 1,12	1,25
A	EP 1 123 713 A (BECTON, DICKINSON AND COMPANY) 16 August 2001 (2001-08-16) abstract; figure 4	1,25
A	US 5 215 536 A (LAMPROPOULOS ET AL) 1 June 1993 (1993-06-01) abstract	1,25
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the International search

4 October 2005

Date of mailing of the international search report

18/10/2005

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## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US2005/022427

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 205 825 A (ALLISON ET AL) 27 April 1993 (1993-04-27) abstract -----	1,25

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Information on patent family members

International Application No

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